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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/944,079 | 09/04/2001 | Atsushi Suzuki | 213502US0 | 1164 |

22850 7590 10/21/2002
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| EXAMINER |
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COE, SUSAN D

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| ART UNIT | PAPER NUMBER |
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1654

DATE MAILED: 10/21/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|---------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/944,079 | SUZUKI ET AL. |
| Examiner | Art Unit | |
| Susan Coe | 1654 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 07 August 2002 and 03 September 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-18 is/are pending in the application.

4a) Of the above claim(s) 1-5,8,9,11-14 and 16-18 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 6,7,10 and 15 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. The amendment filed August 7, 2002, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 7-18 have been added.
3. Claims 1-18 are pending.
4. The declaration filed September 3, 2002 has been considered.

Election/Restrictions

5. In Paper No. 6, dated February 19, 2002 Applicant's election with traverse of Group II, claim 6, now including new claims 7-18, chlorogenic acid for species A, and organic acid having a molecular weight of 60 to 300 for species B. The declaration submitted September 3, 2002 shows unexpected results for the examined combination of chlorogenic acid and Vitamin C; therefore, this species is considered free of the art and an additional species has been selected for examination. The species selected for examination is lactic acid for species B. Chlorogenic acid is still examined for species A.

6. Claims 1-5, 8, 9, 11-14, and 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

7. Claims 6, 7, 10, and 15 are examined on the merits.

Claim Rejections - 35 USC § 112

8. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 specifically excludes citric acid from the composition; however, claim 15 contains citric acid as a member of the Markush group. This conflict is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 6, 7, and 10 is rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,958,417.

Applicant's claims are directed towards a method of treating hypertension using chlorogenic acid and an organic acid with a molecular weight between 60 and 300.

US '417 teaches that Crataegus is used to treat hypertension. The reference states that the active ingredients include chlorogenic acid and caffeic acid (an organic acid with a molecular weight of 180) (see column 2, lines 55-63). Therefore, in using Crataegus to treat hypertension, a composition of chlorogenic acid and an organic acid with the claimed molecular weight has been used.

Claim Rejections - 35 USC § 103

10. Claims 6, 7, 10, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,958,417 and US Pat. No. 4,981,852.

Applicant's claims are drawn to a method of treating hypertension using a composition of chlorogenic acid and lactic acid.

US '417 teaches that the plant Crataegus is used to treat hypertension. An active component in Crataegus is chlorogenic acid (see column 2, lines 55-63).

US '852 teaches using lactic acid to treat hypertension (see claims).

These references show that it was well known in the art at the time of the invention to use chlorogenic acid and an organic acid to treat hypertension. It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used to treat hypertension, an artisan of ordinary skill would have a reasonable expectation that a combination of the two substances would also be useful in treating hypertension. Therefore, the artisan would have been motivated to combine chlorogenic acid and an organic acid together to treat hypertension. No patentable invention resides in combining old ingredients of known properties

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where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

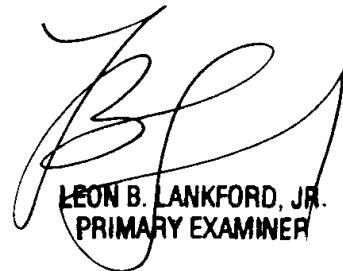
11. No claims are allowed. The method of using the combination of chlorogenic acid and ascorbic acid (Vitamin C) to treat hypertension is considered free of the art based on the declaration submitted September 3, 2002 and the translation of the foreign priority documents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
October 16, 2002



LEON B. LANKFORD, JR.
PRIMARY EXAMINER